APR 1 2 2001

ATTACHMENT 11
510(K) SUMMARY

K010942

U04 endourological R/F system

Submitted by:
Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

March 9, 2001

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. Contact Person

Ms. Amy Shaw Hosler
Phone: (732) 321-4830
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2. Device Name and Classification

Trade Name:	U04
Classification Name:	Image Intensified Fluoroscopic X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1650
Device Class:	Class II
Device Code:	90JAA

3. Indications for Use:

The U04 is an image intensified fluoroscopic X-ray system, primarily for urological applications (functional x-ray diagnostics, endourology and minimal invasive urology/surgery). The system, which includes a radiologic/urologic treatment table, may be used for urological gastroenterological and gynecological treatment, planning and diagnostic procedures including:

- Querying and retrieving patient history information and/or previous diagnosis and images from other modalities.
- X-ray examinations of the urogenital area (e.g. cystoscopy, kidney, bladder, ureter, urethra) including KUB, IVP, vasovesiculography, reflux-cystogram, cystourethrogram, and micturation cystourethrogram combined with uroflow measurements.
- Ultrasound examinations (in conjunction with a stand-alone ultrasound system) of the kidney, bladder, prostate, scrotum.
- endourological interventions (e.g. of the urethra, prostate, bladder, sphincter, ostium, kidney and ureter, catheter placement, penile implant placement, transurethral resection of prostate or

bladder, alternative treatment of the BPH, brachytherapy, as well as gynecological procedures requiring radiological support).

- percutaneous interventions (e.g. PCN nephrolithotomy, resection, percutaneous nephrostomy)
- laparoscopy (e.g. cholecystectomy, nephrectomy, lymph node dissection, abdominal testis detection/correction, varicocele).
- application of fistula (kidney/bladder)
- simple procedures (e.g. urethra, testis, phimosis)
- intracorporeal shock wave lithotripsy
- uroflow/urodynamics
- pediatric radiological and therapeutic applications.

4. Substantial Equivalence

The U04 system is substantially equivalent to Urosokop D3 (K923049) and ICONOS R200 (previously referred to as URF Digital OT, K992660).

5. Device Description

The U04 system is a fluoroscopic X-ray system intended for use in urological applications (functional x-ray diagnostics, endourology and minimal invasive urology/surgery) with an undertable image intensifier. The system is operated either via tableside handheld control or via handheld control at the control desk of the image system.

The U04 system is available in two versions, the U04 high end and U04 mid tier.

6. Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Device

The U04 system has the same technological characteristics as the predicate Uroskop D3. Like the Uroskop D3, the U04 consists of the basic system (patient support table) and standard system components (i.e. X-ray generator, X-ray tube, image intensifier, TV system, digital imaging system, monitors).

The Uroskop D3 and the U04 differ such that, in the U04:

- The basic system and system stand are based on components of the Iconos R200 system.
- A new digital imaging system with CCD camera has been added.
- The unit is configured with the latest commercially available system components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 2 2001

Siemens Medical Systems, Inc.
c/o Mr. Reiner Krumme
TUV Rheinland of North America, Inc.
12 Commerce Road
NEWTOWN CT 06470

Re: K010942
U04 X-ray System
Dated: March 9, 2001
Received: March 29, 2001
Regulatory class: II
21 CFR 892.1650/Procode: 90 JAA

Dear Mr. Krumme:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

ATTACHMENT 1
INDICATIONS FOR USE

510(k) Number (if known): K010942

Device Name: U04

Indications for Use:

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Concurrence of the CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010942

Prescription Use ✓ OR Over-The-Counter Use _____
(per 21 CFR 801.109)